



BILLING CODE: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

**Name:** Advisory Committee on Heritable Disorders in Newborns and Children

**Dates and Times:** November 3, 2015, 9:00 a.m. to 4:00 p.m.

**Place:** Webinar

**Status:** The meeting will be open to the public. Please register at <https://www.blsmeetings.net/ACHDNCNovember2015/>. The registration deadline is Friday, October 30, 2015, 11:59 PM Eastern Time.

**Purpose:** The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by the Public Health Service Act (PHS), Title XI, § 1111 (42 U.S.C. 300b-10), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and

children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

**Agenda:** The meeting will include: (1) discussion and vote on the statutory Committee's proposed bylaws, (2) a discussion of nomination process for prospective organizational representatives, (3) a presentation on the Notice of Proposed Rulemaking on Federal Policy for the Protection of Human Subjects and the potential impact on newborn screening research, (4) updates from the Pilot Study Workgroup, Cost Analysis Workgroup, and Timeliness Workgroup, (5) a presentation on transition models from pediatric to adult health care using innovative strategies, and (6) a presentation on current education activities within newborn screening and impact on families and children. There are no votes that involve proposed additions of a condition to the RUSP scheduled for this meeting.

Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's website at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

**Registration:** Registration information will be on the Committee website at <https://www.blsmeetings.net/ACHDNCNovember2015/>. The registration deadline is Friday, October 30, 11:59 PM Eastern Time.

**Public Comments:** Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. Advance registration is required to present oral comments and/or submit written comments. Oral public comments are tentatively scheduled for November 3, 2015. Individuals who wish to present oral public comments must indicate this when registering. Written comments may be uploaded on the registration website and must be received by the registration deadline (October 30, 11:59 PM Eastern Time), as this will allow them to be included in the November meeting briefing book. Individuals who wish to present oral comments and/or provide written comments should identify on the registration website the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: [lvasquez@hrsa.gov](mailto:lvasquez@hrsa.gov).

**Contact Person:** Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W68, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: [dsarkar@hrsa.gov](mailto:dsarkar@hrsa.gov).

More information on the Advisory Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Jackie Painter

Director, Division of the Executive Secretariat

[FR Doc. 2015-26524 Filed: 10/19/2015 08:45 am; Publication Date: 10/20/2015]